**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**
**CAMDEN VICINAGE**

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| IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION<br><br>This document relates to:<br><br>*All Actions* | No. 19-md-2875-RBK<br>Hon. Robert Kugler |

**MEMORANDUM OF LAW IN SUPPORT OF THE MEDICAL MONITORING PLAINTIFFS' MOTION FOR CLASS CERTIFICATION**

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## I. INTRODUCTION

This multidistrict litigation ("MDL") arises out of one of the largest class I prescription pharmaceutical recalls in United States history, due to contamination of valsartan[1] blood pressure medications with extremely potent human carcinogens, N-nitrosodimethylamine ("NDMA") and N-nitrosodiethylamine ("NDEA").[2] The contamination was the direct result of the Defendants' gross violations of state law and parallel federal regulations, including those regarding good manufacturing practices ("cGMPs").

As relevant to the Medical Monitoring Plaintiffs' claims, Defendants' misconduct resulted in Plaintiffs' exposure to these carcinogens, giving them significantly increased risk of developing cancer. Expert opinion common to the class confirms that a monitoring program is feasible; decades of law confirm monitoring is warranted as a legal matter, and imperative as a matter of basic efficiency and justice.

The Medical Monitoring Plaintiffs, like the Economic Loss Plaintiffs, have asserted class claims against numerous Active Pharmaceutical Ingredient ("API") Manufacturers, Finished Dose ("FD") Manufacturers, three Wholesalers Defendants, and eight Retail Pharmacy Defendants. In addition to class cases, there are also nearly one thousand (1,000) personal injury cases consolidated before this Court. Of course, not all those who *will* develop cancer due to Defendants' conduct have done so, necessitating monitoring.

This Memorandum of Law supports the Medical Monitoring Plaintiffs' Motion for Class Certification. Plaintiffs seek certification of a claim for medical monitoring (brought by plaintiffs who reside in states whose law permits medical monitoring to be an independent claim, on behalf

[1] Valsartan and Valsartan Containing Drugs ("VCDs") are the generic versions of the reference listed drugs ("RLDs") DIOVAN® and/or EXFORGE®, which were the brand names.

[2] Capitalized terms in this brief have the same meanings as in the Economic Loss Brief.

of themselves and others who reside in those states). They also seek certification of a class for their entitlement to the remedy of medical monitoring (brought by plaintiffs who reside in states that permit medical monitoring as a remedy, on behalf of themselves and others who reside on those states).

At a high level, certification of the medical monitoring claims should follow ineluctably from certification of the Economic Loss Claims for two reasons. First, the same common evidence presented by the Economic Loss Plaintiffs that shows that questions about Defendants' wrongful conduct should be answered in one class proceeding—rather than the alternative of millions of separate proceedings, or more realistically none at all—applies here. Second, to the extent the Medical Monitoring Plaintiffs must prove distinct elements from Economic Loss, those elements are paradigmatic examples where proof is *necessarily group wide*, as shown below. Certification under Rule 23(b)(2)—or, in the alternatively with respect to the independent claim class only, Rule 23(b)(3)—is warranted.

## II. RELEVANT PROCEDURAL AND FACTUAL BACKGROUND

### A. Procedural History

Medical Monitoring Plaintiffs incorporate the procedural history from Section II of the Economic Loss Plaintiffs' Memorandum in Support of Motion for Class Certification ("EL Brief"), filed concurrently herewith. Like the Economic Loss Plaintiffs, the Medical Monitoring Plaintiffs bring claims for relief against Defendants—Manufacturers, Wholesalers, and Retailers—for Defendants' common, classwide conduct in the production and/or sale of contaminated Valsartan. Following the Court's thorough rulings on the pleadings, Medical Monitoring Plaintiffs' Third Amended Consolidated Medical Monitoring Complaint ("Complaint") brings claims under the law of warranty, fraud, negligence, and products liability,

in addition to the independent claim for medical monitoring.[3] *See* Dkt. No. 1709. Medical Monitoring Plaintiffs seek a classwide remedy in the form of a medical monitoring program, with conservatively defined membership, designed by qualified experts, and instituted and overseen by the Court.

### B. Factual Background

The Medical Monitoring Plaintiffs are individuals residing in the United States who consumed generic valsartan to treat their high blood pressure. *See* Dkt. No. 1709 at ¶¶ 538-546. Medical Monitoring Plaintiffs depended on these medications for their health, and on Defendants to manufacture, distribute, and dispense a generic product that was bioequivalent to the brand variety. *See* Dkt. No. 1709 at ¶¶ 117, 354, 361. Instead, Defendants manufactured and distributed generic valsartan contaminated with nitrosamines at the time Medical Monitoring Plaintiffs and Class Members consumed it. Nitrosamines, specifically NDMA and NDEA, are human carcinogens. By consuming Defendants' adulterated products—valsartan-containing drugs ("VCDS")—Medical Monitoring Plaintiffs, each of whom has consumed a sufficient amount of adulterated valsartan such that they now face a significantly increased risk of cancer, are entitled to medical monitoring, as addressed below.

#### 1. Common Sources of Evidence Relating to Defendants' Underlying Wrongful Conduct.

The background detailing Defendants' wrongful conduct, inadequate manufacturing processes, breach of their obligations and representations, and the nature of the contamination—and how this conduct uniformly applied apply to each Class Member—is set forth in the

[3] Specifically, the claims are (1) negligence; (2) negligence *per se*; (3) negligent misrepresentation and omission; (4) medical monitoring; (5) products liability – manufacturing defect; (6) failure to warn; (7) breach of implied warranty of merchantability; (8) breach of express warranty; (9) fraud and fraudulent concealment; and (10) claims under state law product liability acts. Plaintiffs include a summary of each claim's applicability in Exhibit A.

Economic Loss Plaintiffs' brief. Medical Monitoring Plaintiffs incorporate Section III of the EL Brief. In summary, common sources of proof will show that the generic valsartan manufacturing process caused a chemical reaction producing nitrosamines, introducing nitrosamine contamination into the finished VCD product. *See* EL Brief, Section III. The contamination resulted in classwide exposure to a human carcinogen, in derogation of Manufacturer Defendants' responsibilities and duties to oversee their processes and other obligations.

Likewise, common evidence will show that the Wholesaler Defendants, who purchased VCDs from the Manufacturer Defendants, failed to ensure that the VCDs they purchased were of adequate quality or in compliance with FDA regulations and analogous state law. Once introduced into interstate commerce, the Retail Pharmacy Defendants received VCDs from the Wholesaler Defendants and dispersed them to Class Members; the Retail Pharmacy Defendants failed, on a common, classwide basis, to ensure that the VCDs were appropriately sourced.

**2. Common Sources of Evidence Relating to Increased Risk.**

Each Defendant's affirmative wrongful conduct and failures to act resulted in classwide exposure to VCDs and a significantly increased risk of cancer, which risk is demonstrable on a classwide basis. The attached reports from Drs. Madigan and Panigrahy, Exhibits B and C respectively, demonstrate, using dietary and other studies, that there is a threshold NDMA Lifetime Cumulative Exposure associated with statistically significant increased risks of developing cancers. These studies, and the threshold Lifetime Cumulative Exposure figures extracted from them, constitute common sources of evidence for increased risk resulting from exposure to VCDs. The Classes have been conservatively defined taking into account common sources of evidence of increased risk. *See* Section III.A, *infra*.

### 3. Common Sources of Evidence Relating to the Proposed Medical Monitoring Program.

Finally, all questions about the specifics of the Medical Monitoring sought by the Class, including its contours, feasibility, and costs, are necessarily common and classwide. The common evidence here consists of expert reports.

In light of the elevated risk of developing esophageal, stomach, colorectal/intestinal, liver, lung, bladder, blood, pancreatic, and prostate cancer, the Class Members require additional targeted testing. Dr. Kaplan, M.D.[4], the Chairman of the Department of Hematology and Oncology at Rush North Shore Medical Center, Assistant Professor of Medicine at Rush Medical College, and practicing oncologist, has crafted a proposed monitoring program. In so doing, he demonstrates that common evidence will show the feasibility of a plan. *See* Exhibit D, Report of Dr. Edward Kaplan ("Kaplan Report").

The proposed program would provide reasonable and necessary screening mechanisms for the abovementioned cancers. *Id.* at 3-4. These screening mechanisms include, for each Class Member, an annual Cologuard test, or similar fecal occult testing for colon cancer; low dose CT chest scan; urinalysis; blood smear evaluation (CBC); and Galleri multi-cancer early detection blood test, or similar liquid biopsy. *Id.* at 4-6. Every five years, each Class Member would receive a colonoscopy and upper endoscopy under the proposed program. *Id.* Dr. Kaplan details in his report that this proposed monitoring program is different than one that would have been prescribed in the absence of the increased risk caused by the classwide exposure to VCDs. *Id.* at 6.

Dr. Song, an associate professor of health care policy at Harvard Medical School and a

[4] M.D., Loyola-Stritch School of Medicine; Internship and Residency training, Northwestern University Medical School.

general internist at Massachusetts General Hospital, with an M.D. from Harvard Medical School and a Health Policy Ph.D.[5] from Harvard University, has shown the common cost inputs to this program. *See* Exhibit E, Expert Report of Dr. Zirui Song ("Song Report").

## III. THE PROPOSED CLASS DEFINITION, CLASS EXCLUSIONS, AND CLASS ASCERTAINABILITY

### A. Proposed Class Definitions and Exclusions.

The Medical Monitoring Plaintiffs move to certify two classes, covering all states that allow medical monitoring as an independent claim for relief or as a remedy. Plaintiffs seek certification of an Independent Claim Class under Federal Rule 23(b)(2) or (b)(3). The Independent Claim Class is:

> All individuals residing in Alaska, Arizona, Colorado, Delaware, District of Columbia, Florida, Hawaii, Idaho, Illinois, Iowa, Maine, Massachusetts, Minnesota, Missouri, Montana, Nevada, New Hampshire, New Mexico, New York, North Dakota, Oregon, Pennsylvania, Rhode Island, South Dakota, Utah, Vermont, West Virginia, Wyoming and who consumed a sufficiently high Lifetime Cumulative Threshold of NDMA, NDEA, or other nitrosamine, in generic valsartan-containing drugs manufactured by or for Defendants and marketed in the United States and its territories and possessions, at least since January 1, 2012.

*See* Complaint, Dkt. No. 1709, at ¶ 538.

Plaintiffs also seek certification of a Remedy Class under Federal Rule 23(b)(2). The Remedy Class is:

> All individuals residing in every state, territory, and possessions of the United States of America except Mississippi and who consumed a sufficiently high Lifetime Cumulative Threshold of NDMA, NDEA, or other nitrosamine, in generic valsartan-containing drugs manufactured by or for Defendants and marketed in the United States and its territories and possessions, at least since January 1, 2012. This is the "Medical Monitoring Remedy Class."

[5] Concentration in economics.

*Id.* at ¶ 539. These class definitions reflect the Court's Orders on the Motions to Dismiss, as well as the Special Master's Order on Plaintiffs' Motion for Leave to Amend. *See* Dkt. Nos. 838, 1614. Excluded from the Independent Claim and Remedy Classes are "Defendants and their subsidiaries and affiliates; all persons who make timely election to be excluded from the Classes to the extent any class is an opt-out class or a hybrid opt-out class; governmental entities; and any judicial officers who preside over this case and their immediate family members. Also excluded from the Classes are those consumers of VCDs who have been diagnosed with cancers as a result of taking Defendants' NDMA-, NDEA-, or other nitrosamine-contaminated VCDs." *Id.* at ¶ 543.

The class structure reflects the one arguably meaningful difference between and among the laws of the different states: some states permit medical monitoring as an independent claim, while others only permit medical monitoring as a remedy for an underlying claim. Medical Monitoring Plaintiffs present proposed Class Representatives who are able to represent each class because of their residence. The Medical Monitoring Plaintiffs note that in this action there are no practical differences between the two proposed classes, given that Defendants have engaged in uniform conduct that applies to all Class Members regardless of where they reside.

The Medical Monitoring Classes satisfy the requirements of Rule 23(a) and 23(b). However, even if the Court did not certify one of the legal claims brought by the Economic Loss Plaintiffs, the Court could still certify at a minimum the Medical Monitoring Independent Claim Class who seek monitoring relief based on a separate, standalone medical monitoring cause of action. Further, and underscoring why certification of the Medical Monitoring Classes follows logically from certification of the Economic Loss Classes due to the facts of the case, the Medical Monitoring Class Members substantially overlap with the Economic Loss Class

Members.

**B. Both Medical Monitoring Classes are Ascertainable.**

Medical Monitoring Plaintiffs incorporate the EL Brief's discussion of the Third Circuit's implied requirement of ascertainability as applicable to (b)(3) classes, which the Independent Claim Class seeks in the alternative.[6] *See generally*, EL Brief, Section IV.D. Simply, ascertainability requires only that "(1) the class is defined with reference to objective criteria and (2) there is a reliable and administratively feasible mechanism for determined whether putative class members fall within the class definition." *Id.* (quoting *Byrd*, 784 F.3d at 163). Plaintiffs need not identify all Class Members at the certification stage—"a plaintiff need only show that class members can be identified." *Hargrove v. Sleepy's LLC*, 974 F.3d 467, 470 (3d Cir. 2020). Ascertainability is shown through business records, affidavits, and other "reliable evidence." *Select Auto Sales Inc. v. BMW of N. Am. Inc.*, 867 F.3d 434, 441 (3d Cir. 2017).

Medical Monitoring Plaintiffs have defined both Classes with reference to objective criteria. The determination of whether the Class Member consumed a Lifetime Cumulative Threshold sufficient for Class membership is based on dosage, API manufacturer, and time period: (A) at a dose of 320 mg, the Class Member needs to have taken a combination of three (3) months of ZHP API, OR 18 months of Hetero API, OR 54 months of Mylan and/or Aurobindo API; (B) at a dose of 160 mg, the Class Member needs to have taken a combination of six (6) months of ZHP API, OR 32 months of Hetero API, OR 108 months of Mylan and/or Aurobindo API; (C) at a dose of 80 mg, the Class Member needs to have taken a combination of 12 months of ZHP API, OR 64 months of Hetero API, OR 216 months of Mylan and/or Aurobindo API; and (D) at a dose of 40 mg, the Class Member needs to have taken a

[6] Ascertainability is not a requirement for a (b)(2) class seeking only injunctive and declaratory relief. *Shelton v. Bledsoe*, 775 F.3d 554, 563 (3d Cir. 2015).

combination of 24 months of ZHP API, OR 128 months of Hetero API, OR 432 months of Mylan and/or Aurobindo API. *See* Dkt. No. 1709 at ¶¶ 541-42.

This information can be determined by examining pharmacy and prescription records, and by reference to the unique 10-digit NDC code issued to all generic drug products. *See* Declaration of Laura R. Craft ("Craft Decl.") at ¶¶ 2, 9.[7] NDC codes provide information about the strength of the valsartan, dosage form, package size, and type, and remain with a specific drug product for its entire life. Craft Decl. at ¶ 15. NDC codes are standardized across all drugs in the United States (including generics, which receive their own unique NDC, Craft Decl. at ¶ 15), and therefore the availability of an NDC code "makes it possible to construct a consumption record" for Class Members. Craft Decl. at ¶ 51.

Each Pharmacy Defendant is required to retain prescription drug records for at least 10 years in compliance with Medicare and Medicaid requirements, Craft Decl. at ¶¶ 43-50—because the Class Period begins in 2012, the pharmacy and prescription records of every putative Class Member is also within the databases controlled by Defendants. See, e.g., Craft Decl. at ¶ 72. Such records will—as they are required to—contain the NDC Code and dosage information necessary to determine Class membership. Craft Decl. at ¶¶ 15, 33-35.

This approach is similar to that in other medical monitoring cases, where courts have defined classes based on specific use of the product. *In re Telectronics Pacing Sys., Inc.*, 172 F.R.D. 271, 278-79 (S.D. Ohio 1997) (court similarly defined the class in that case with reference to the model number of a pacemaker); *see also Reilly v. Gould, Inc.*, 965 F. Supp. 588, 596 (M.D. Pa. 1997) (proper to geographically limit class membership to ensure minimum threshold exposure was met); *O'Connor v. Boeing N. Am., Inc.*, 180 F.R.D. 359, 368 (C.D. Cal.

[7] The Craft Declaration is filed as part of the Economic Loss Plaintiffs' Motion.

1997) (collecting cases showing that classes by defined around exposure levels—reflected in those cases by geography—was permissible); *cf. Byrd v. Aaron's Inc.*, 784 F.3d 154, 171 (3d Cir. 2015) ("the size of a potential class and the need to review individual files to identify its members are not reasons to deny class certification."); Craft Decl. at ¶ 72.

## IV. MEDICAL MONITORING CLAIMS ARE SUITABLE FOR CLASS TREATMENT

Medical monitoring is a quintessential collective remedy or cause of action available to a population exposed to a heightened risk of injury. Medical monitoring focuses on the shared risk faced by the proposed class and the need for a monitoring program common to all those exposed. Courts recognize these characteristics of medical monitoring claims and often certify medical monitoring class actions. *See, e.g.*, *Baker v. Sorin Grp. Deutschland GMH*, No. 16-00260, 2017 U.S. Dist. LEXIS 235430 (M.D. Pa. Oct. 23, 2017) (certifying medical monitoring class under Rule 23(b)(2)); *In re Diet Drugs Prods. Liab. Litig.*, No. 98-20626, 1999 WL 673066 (E.D. Pa. Aug. 26, 1999) (certifying medical monitoring class under Rule 23(b)(2)); *Donovan v. Philip Morris USA*, 268 F.R.D. 1 (D. Mass. 2010) (holding that proposed medical monitoring class satisfied Rule 23(b)(2) and 23(b)(3)); *Telectronics*, 172 F.R.D. at 290.

Courts have certified medical monitoring classes under Rule 23(b)(2) and Rule 23(b)(3). The Third Circuit has not ruled on whether medical monitoring claims (as a cause of action or as a classwide remedy) are injunctive in nature. *See Barnes v. Am. Tobacco Co.*, 161 F.3d 127, 132 (3d Cir. 1998) (citing but not ruling on district court's analysis that "relief requested under a medical monitoring claim can be either injunctive or equitable in nature."). However, courts within this Circuit have held that medical monitoring is indeed injunctive, and have accordingly found medical monitoring suitable for certification under Rule 23(b)(2). For example, in *In re Diet Drugs* the court conducted a detailed analysis of the medical monitoring program requested

by the class, all of whom faced an increased risk of heart valve injury from ingesting "fen-phen" drugs. 1999 WL 673066, at *6-8. The program requested diagnostic testing, and the collection and research of medical data. The court concluded that the requested relief was injunctive in nature, suitable for class treatment under Rule 23(b)(2). *Id.*

More recently, Judge Jones also ruled that a class of individuals exposed to bacterial infection during surgery were seeking injunctive relief by requesting a court-appointed monitoring program. *See Baker*, No. 16-00260, 2017 U.S. Dist. LEXIS 235430, at *23-24 (analyzing (b)(2) certification after *Wal-Mart Stores, Inc. v. Dukes, et. al*, 564 U.S. 338 (2011)). In *Baker*, plaintiffs sought (b)(2) certification of a class that had suffered exposure to a single bacterium while undergoing a medically necessary surgery. Outside the Third Circuit, courts have also found medical monitoring to be a form of injunctive relief, and have certified medical monitoring classes under Rule 23(b)(2). *See, e.g.*, *Day v. NLO, Inc.*, 144 F.R.D. 330, 335-36 (S.D. Ohio 1992) (holding that medical monitoring constituted injunctive relief and certifying (b)(2) class), *rev'd on other grounds*, 5 F.3d 154 (6th Cir. 1993).

Alternatively, medical monitoring classes may be certified under Rule 23(b)(3), provided Plaintiffs can establish the requirements of predominance and superiority. For example, in *In re Telectronics*, the court certified a class of individuals who sought medical monitoring after receiving defective pacemaker implants, and found that the class satisfied the predominance and superiority requirements of Rule 23(b)(3). 172 F.R.D. at 286-87 (noting that the affirmative defense and the nature of the alleged defect predominated over individual issues, and that a class action was superior). More recently, in *Donovan*, the court found that a class of smokers seeking medical monitoring relief was properly certifiable under Rule 23(b)(3). 268 F.R.D. at 28. It is notable that the court found that "[b]ecause all seven elements of the medical monitoring cause

of action may be proven on a class-wide basis . . .plaintiffs' common issues predominate." *Id.* at 28-29.

Finally, in the settlement context, courts have certified classes seeking medical monitoring and have overseen comprehensive class-wide monitoring programs. Medical Monitoring Plaintiffs note this fact because it underscores that even complex monitoring programs are feasible and manageable. For example, in the diet drug "fen-phen" cases, a district court in this Circuit approved a medical monitoring settlement class consisting of millions of individuals who faced an increased risk of heart valve damage by taking these drugs. *See In re Diet Drugs*, 2000 WL 1222042, at *6-7 (E.D. Pa. Aug. 28, 2000). The class was defined to include those who took a sufficient amount of the at-issue drugs—functionally similar to the limitations Medical Monitoring Plaintiffs propose here—and requested court-administered medical monitoring program that consisted of echocardiograms, cardiologist consultations, x-rays, laboratory studies, and other monitoring and diagnostics. *Id.* at *18-20. The court, in approving the settlement (valued at more than $4.5 billion), noted that the class and the requested relief satisfied the requirements of Rule 23(b)(2) and the superiority considerations in Rule 23(b)(3). *Id.* at *54-55.

More recently in the settlement class context, in the NCAA concussion litigation, the court certified a medical monitoring settlement class and found that the requirements Rule 23(b)(2) were satisfied. *In re NCAA Student-Athlete Concussion Injury Litig.*, 314 F.R.D. 580, 599 (N.D. Ill. 2016). In *NCAA*, the program involved specialized medical evaluations of thousands of former and current college athletes, including behavioral, mood, and neurological analyses. *Id.* at 605-06. Medical monitoring cases are thus suitable for class treatment.

## V. BOTH CLASSES SATISFY THE REQUIREMENTS OF RULE 23(a) AND RULE 23(b)

### A. Common Evidence as to the Elements of an Independent Medical Monitoring Claim and Medical Monitoring Relief.

The common evidence at trial to establish an independent medical monitoring claim for the Independent Claim Class will be virtually identical to the evidence to establish entitlement to a medical monitoring remedy as to the Remedy Class. Accordingly, Medical Monitoring Plaintiffs describe the common evidence for the elements of a medical monitoring claim, which evidence is likewise applicable to the Remedy Class.

In the states that recognize medical monitoring as an independent cause of action (such as Pennsylvania), the elements are: (1) exposure; (2) to a toxic substance or hazard; (3) which exposure was caused by the defendants' negligence or tortious conduct; (4) result in an increased risk of a serious illness or injury; (5) for which a medical test for early detection exists, (6) is reasonably necessary, and (7) is beyond that which is offered in the ordinary course. *See e.g.*, *Redland Soccer Club, Inc. v. Dep't of the Army & Dep't of Def. of the U.S.*, 696 A.2d 137, 145-46 (1997).[8] Medical Monitoring Plaintiffs can and will prove each of these elements using common evidence.

[8] Similarly in Massachusetts, medical monitoring requires that "(1) the defendant's negligence (2) caused (3) the plaintiff to become exposed to hazardous substance that produced, at least, subcellular changes that substantially increased the risk of serious disease, illness, or injury (4) for which an effective medical test for reliable early detection exists, (5) and early detection, combined with prompt and effective treatment, will significantly decrease the risk of death or the severity of the disease, illness or injury, and (6) such diagnostic medical examinations are reasonably (and periodically) necessary, conformably with the standard of care, and (7) the present value of the reasonable cost of such tests and care, as of the date of the filing of the complaint." *See Donovan v. Philip Morris USA, Inc.*, 914 N.E.2d 891, 902 (Mass. 2009); *Hansen v. Mountain Fuel Supply Co.*, 858 P.2d 970, 979 (Utah 1993) (requiring similar elements). Indeed, "[o]f the states that do recognize medical monitoring as an independent cause of action, the elements of such a claim appear to be same." *In re Baycol Prods. Litig.*, 218 F.R.D. 197, 211-12 (D. Minn. 2003) (collecting cases).

**1. Element One: Exposure.**

The Independent Claim Class Members' consumption of nitrosamine-contaminated valsartan is a common issue, demonstrated by common records of prescription. Plaintiffs use a Lifetime Cumulative Threshold to determine the minimum exposure from consumption of VCDs, which consumption is readily determinable by looking at the Plaintiff Fact Sheets and pharmacy records—and either the Class Member meets this threshold or does not. The exposure threshold is established using a straightforward points system that has classwide applicability. Class Members here suffer ongoing, certain exposure by dint of consuming the contaminated valsartan.

If there are individual issues at all, they are eclipsed by (and not predominate over) common ones. In *Baker*, for example, the court explained that exposure arising from an experience shared by all class members could require consideration of individual issues (i.e., whether they had the surgery at issue or not), but held that "[t]he necessity of proving one threshold fact for each class member is certainly not significant or predominant in light of all of the other factual and legal issues common to the class." *Baker*, No. 16-00260, 2017 U.S. Dist. LEXIS 235430, at *30. Here too, establishing whether a Class Member has reached a threshold exposure to nitrosamines creating a significantly increased risk is a question shared by all Class Members, and is central to the resolution of all Class Members' claims.

**2. Element Two: To a Hazardous Substance.**

To prove this element, generally plaintiffs must show "scientific evidence demonstrating a probable link between exposure to a particular compound and human disease." *Bower v. Westinghouse Elec. Corp.*, 522 S.E.2d 424, 433 (W. Va. 1999). This element can be established with common proof because the focus is on nitrosamine contamination in valsartan—a contamination common to the entire class—and whether such contamination leads to a

significantly increased risk of cancer.

Plaintiffs will show common evidence that Defendants' contaminated valsartan products present a significant and unacceptable risk to Class members. *See* Exhibit B at 9-10; Exhibit C at 222. And, of course, whether NDMA and NDEA, and other nitrosamines, are human carcinogens is a common question (and one with an established answer in the affirmative, at that). *See* Dkt. No. 1709 at ¶¶ 318-338. Plaintiffs will also show common evidence that exposure to threshold levels of nitrosamines render a medical monitoring program medically reasonable.

### 3. Element Three: Due to Defendant's Negligence/Tortious Conduct.

Plaintiffs can establish this element using common evidence of Defendants' actions and knowledge, and the contaminated valsartan itself—this evidence does not depend on any Class Member's individual circumstances. Here, Medical Monitoring Plaintiffs refer to and incorporate the EL Brief for the common evidence of, and the law showing the propriety of certification of, the warranty and fraud claims.[9]

For example, whether the Manufacturer Defendants owed a duty to Class members is a common question that can be resolved class-wide, as are the questions of whether Defendants' conduct was fraudulent. The possibility of individualized questions regarding the defenses Defendants may raise does not defeat commonality. *See Baker*, No. 16-00260, 2017 U.S. Dist. LEXIS 235430, at *34 (M.D. Pa. Oct. 23, 2017).

Likewise with respect to negligence claims, as those brought by the Medical Monitoring Remedy Class, the common evidence that will establish the medical monitoring claims will also establish the breach of duty and causation elements of negligence. *See In re Brinker Data*

[9] The Medical Monitoring Plaintiffs and the Economic Loss Plaintiffs share the bulk of the legal claims, including fraud and warranty.

*Incident Litig.*, No. 18-0686, 2021 WL 1405508, at *14 (M.D. Fla. Apr. 14, 2021) (certification of a nationwide negligence claim). Whether the Defendants owed all Remedy Class Members a duty of care is a common question that stems from the Defendants' obligations as manufacturers, distributors, and retailers is a common question. Moreover, because the Remedy Class seeks medical monitoring relief—a common program for all—and not economic damages, the potentially individualized inquiry of damages is not at issue. Nor are there issues of mitigation or comparative fault, as the common evidence reflects that Plaintiffs in no way used their medicine incorrectly or in a variegated way.

Similarly, the Remedy Class' product liability claims for failure to warn and manufacturing defect are also susceptible to common, classwide proof. This case is similar to *Telectronics*, where the common issue of whether the product was defective was central to resolution of the class' claims. 172 F.R.D. at 288. Accordingly, the Remedy Class' product liability claims can be resolved by answering discrete questions, all of which rely on common evidence.

**4. Element Four: Resulting in Increased Risk.**

This element does not require that Plaintiffs "show that a particular disease is certain or even likely to occur as a result of exposure." *Bower*, 522 S.E.2d at 433. Rather, the Class must establish a "significantly increased risk of contracting a particular disease relative to what would be the case in the absence of exposure." *Id.* No "particular level of quantification is necessary to satisfy this requirement." *Id.*

Plaintiffs will use common evidence, including the use of a Lifetime Cumulative Threshold, to establish an increased risk of cancer classwide. Specifically, Dr. Madigan analyzed dietary and other studies to demonstrate the Lifetime Cumulative Thresholds of NDMA that trigger statistically significant increased risks for different types of cancers. Plaintiffs'

experts reached the conclusion that Defendants' contaminated valsartan products posed an unacceptable risk to Class Members—by examining common evidence, including Defendants' internal data, reports from regulatory agencies, and the valsartan dosages that had been recalled.

### 5. Elements Five, Six, and Seven: A Necessary and Effective Monitoring Program Exists.

The final three elements require that Plaintiffs show the existence of a diagnostic test or program that can mitigate the risks faced by the Class as a result of their exposure to contaminated valsartan, and that this program is "different than the one that would have been prescribed in the absence of that particular exposure." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 788 (3d Cir. 1994); *Gates v. Rohm & Haas Co.*, 655 F.3d 255, 265 (3d Cir. 2011).

Plaintiffs will prove these elements by way of common evidence: their proposed monitoring program. The program is a group remedy—a notice program intended to reach all Class members, followed by a series of medical tests, the costs of which will be paid for by Defendants, designed to monitor for cancers linked to NDMA and NDEA exposure.[10] As Dr. Kaplan has explained, each Class Member shall receive regular cancer screening tests formulated based on medical necessity and risk mitigation. This program provides screening and tests beyond what Class Members would obtain in the absence of exposure to contaminated valsartan Finally, those Class Members who are diagnosed with one of the above-listed cancers will be entitled to the costs of their treatment under the proposed plan.

The program that Plaintiffs propose does not require individualized inquiries into its benefits, or the safety implications for certain Class Members. Here, the monitoring program can mitigate the risk faced by the entire Class. Moreover, the proposed program is administratively feasible—there is well-established infrastructure to provide notice, and to

[10] Esophageal, stomach, colorectal/intestinal, liver, lung, bladder, blood, pancreatic, and prostate

conduct the contemplated tests and screenings. Defendants will be able to track communications to their customers, and there is precedent for this type of monitoring program. Furthermore, Dr. Song's report demonstrates the methodology for calculating the costs of the medical monitoring program. *See* Ex. D, Song Report at 22-26.

The effectiveness, necessity, and feasibility of a medical monitoring program thus are all demonstrable through common evidence.

### B. Both Classes Satisfy the Remaining Requirements of Rule 23(a).

#### 1. Both Classes are Sufficiently Numerous.

Rule 23(a)(1) requires that Plaintiffs show that the "class is so numerous that joinder of all members is impracticable." Fed. R. Civ. P. 23(a)(1). This requirement generally is met when the number of class members exceeds 40. *Stewart v. Abraham*, 275 F.3d 220, 226-27 (3d Cir. 2001). The FDA's voluntary recall of the contaminated valsartan manufactured and distributed by defendants lists over 1,200 unique NDC and Lot Number combinations.[11] Furthermore, by way of example, patient level data from Retail Pharmacy Defendants Walgreens and Rite-Aid shows over 988,183 filled prescriptions of VCDs during the Class Period. Relying on that data, Medical Monitoring Plaintiffs estimate that the Medical Monitoring Classes number *at least* in the thousands. Accordingly, Medical Monitoring Plaintiffs meet the numerosity requirement.

#### 2. Both Classes Satisfy Commonality.

Both the Independent Claim Class and Remedy Class satisfy commonality under Rule 23(a). Rule 23(a)(2) requires that "there are questions of law or fact common to the class." Fed. R. Civ. P. 23(a)(2). In making this determination, courts are to consider "the capacity of a

[11] FDA, FDA UPDATES ON ANGIOTENSIS II RECEPTOR BLOCKER (ARB) RECALLS INCLUDING VALSARTAN, LOSARTAN, AND IRBESARTAN, https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm (last visited, Oct. 24, 2021).

classwide proceeding to generate common answers apt to drive the resolution of the litigation." *Wal-Mart v. Dukes*, 564 U.S. 338, 350 (2011). Although a "single common question" can satisfy Rule 23(a)(2), it "must be of such a nature that [its] determination . . . will resolve an issue that is central to the validity of each one of the claims in one stroke." *Id.* (internal quotation omitted). Additionally, "[t]he focus of the commonality inquiry is not on the strength of each plaintiff's claim, but instead is on whether the defendants' conduct was common as to all of the class members." *Rodriguez v. Nat'l City Bank*, 726 F.3d 372, 382 (3d Cir. 2013) (internal quotation and citations omitted). As Medical Monitoring Plaintiffs have described above, common evidence exists that will prove each element of an independent medical monitoring claim, and that will likewise establish entitlement to medical monitoring as a remedy.

### 3. Plaintiffs' Claims are Typical of Class Members' Claims.

Rule 23(a)(3) requires that a proposed class representative's claims "are typical of the claims or defenses of the class." Fed. R. Civ. P. 23(a)(3). The purpose of this requirement is to assure that the "incentives of the plaintiffs are aligned with those of the class." *Beck v. Maximus, Inc.*, 457 F.3d 291, 295-96 (3d Cir. 2006). The claims of the named Plaintiffs and Class Members need not be identical to satisfy typicality, so long as their claims are based on the same legal or remedial theory. *See In re Prudential Ins. Co.*, 148 F.3d 283, 312 (3d Cir. 1998) (holding that "the various forms [the class representatives'] injuries may take do not negative a finding of typicality, provided the cause of the injuries is some common wrong.").

Here, both Classes' Class Representatives' bring similar claims and seek the same relief. All Class Representatives seek a common medical monitoring program, and each Class Representative meets the Lifetime Cumulative Threshold of exposure to VCDs that is required for Class membership. *See* Dkt. No. 1709 at ¶¶ 538-542.

- Medical Monitoring Plaintiffs Berkson, Kruk, Rives, Rodich-Annese, and Tasker are all proper representatives of the Independent Claim Class. They reside in the following respective states, which states all recognize an independent claim for medical monitoring: Illinois (Berkson, Kruk, and Rives), Pennsylvania (Rodich-Annese), and West Virginia (Tasker). Each of these Independent Claim Class representatives consumed a Lifetime Cumulative Threshold amount of VCDs sufficient to necessitate medical monitoring, which consumption is verifiable by objective, ascertainable records.
- Medical Monitoring Plaintiffs Silberman (New Jersey); Judson, Hamel (California); Zehr (Florida); Berkson, Kruk, Rives (Illinois); Fields, Daring (Maryland); Rodich-Annese (Pennsylvania); Tasker (West Virginia); O'Neill (Kansas); Cotton (Texas); and Bell (Arkansas) are all proper representatives of the Remedy Class. The states in which they reside all recognizing medical monitoring as a form of available relief for an underlying claim, such as negligence, breach of warranty, fraud, or product liability claims. Each of these Independent Claim Class representatives consumed a Lifetime Cumulative Threshold amount of VCDs sufficient to necessitate medical monitoring, which consumption is verifiable by objective, ascertainable records.

The proposed Class Representatives are identically situated with the Class Members, because they all consumed sufficient VCDs to face an increased risk of cancer, which risk is a result of Defendants' wrongful conduct and would all benefit from the proposed monitoring program.

#### 4. Plaintiffs and Proposed Class Counsel Will Fairly and Adequately Represent Class Interests.

Rule 23(a)(4) requires that a proposed class representative "will fairly and adequately protect the interests of the class." Fed. R. Civ. P. 23(a)(4). Adequacy of representation turns on:

(1) whether "the plaintiff's attorney [is] qualified, experienced, and generally able to conduct the proposed litigation," and (2) whether the plaintiff has "interests antagonistic to those of the class." *Wetzel v. Liberty Mut. Ins. Co.*, 508 F.2d 239, 247 (3d Cir. 1975). The proposed class representatives have no conflicts of interest with other Class Members. They, like all Class Members, have consumed valsartan contaminated with nitrosamines, and share the same interest in obtaining monitoring that can mitigate their risk of injury. Further, each of the proposed class representatives has been an active participant in this case: they have provided information to their attorneys, searched for and produced records in response to discovery, including sensitive medical history, and have all sat for depositions or are scheduled to do so.

Proposed Class Counsel will also fairly represent the Class, satisfying Rule 23(g). Here, as established by contemporaneously filed declaration of counsel, proposed Class Counsel have deep experience prosecuting complex class actions, including medical monitoring claims and litigation involving pharmaceutical products, and have committed sufficient resources to prosecuting this case. *See* Exhibit F Rule 23(g) Declaration of Rachel Geman.

### C. Both Classes Satisfy Rule 23(b)(2).

Class certification is appropriate if the proposed class meets the requirements of Rule 23(a) and at least one subsection of Rule 23(b). A district court is afforded considerable discretion to evaluate and "frame issues for consideration under Rule 23[.]" *In re Modafinil Antitrust Litig.*, 837 F.3d 238, 249 (3d Cir. 2016). To satisfy Rule 23(b)(2), Medical Monitoring Plaintiffs must first "seek relief which is predominantly injunctive or declaratory," and second "must complain that defendants acted or refused to act on grounds generally applicable to the class." *Barabin v. Aramark Corp.*, 210 F.R.D. 152, 160 (E.D. Pa. 2002), *aff'd*, No. 02-8057, 2003 WL 355417 (3d Cir. Jan. 24, 2003).

Both Classes seek relief that is exclusively equitable and injunctive, and therefore

certification under Rule 23(b)(2) is appropriate. *See Baker*, No. 16-00260, 2017 U.S. Dist. LEXIS 235430, at *340; *In re Diet Drugs*, 1999 WL 673066. In *Baker*, Judge Jones discussed the holdings of other district courts that analyzed the nature of court-administered medical monitoring programs, and concluded that such relief was predominantly injunctive. *Baker*, No. 16-00260, 2017 U.S. Dist. LEXIS 235430, at *19-21. In the "fen-phen" cases, the court also found that seeking medical monitoring for exposure to a defective drug was a form of injunctive relief. *In re Diet Drugs*, 1999 WL 673066 at *6-7. Here, Plaintiffs specifically seek a court-administered medical monitoring program, and do not seek monetary compensation—this relief is quintessentially injunctive, and accordingly this requirement of Rule 23(b)(2) is satisfied.

The second requirement—that defendants act or refused to act on grounds generally applicable to the class—is subsumed under the cohesiveness analysis in this Circuit. *In re Diet Drugs*, 1999 WL 673066, at *9-10. Cohesiveness means, therefore, that a court must "find that a defendant has acted on grounds generally applicable to the proposed class." *Agostino v. Quest Diagnostics Inc.*, 256 F.R.D. 437, 456 (D.N.J. 2009). The nature of the cohesiveness analysis is substantially similar to the predominance analysis conducted under Rule 23(b)(3). Accordingly, the class must be "cohesive" such that the members "have strong commonality of interests." *Gates v. Rohm & Haas Co.*, 655 F.3d 255, 263–64 (3d Cir. 2011). The analytical approach used to determine predominance under Rule 23(b)(3) may be used to determine cohesiveness under Rule 23(b)(2). *See In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 311 (3d Cir. 2008).

One way to establish cohesiveness is if the "essential elements of the cause of action" do not require individual treatment. *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 172 (3d Cir. 2001), *as amended* (Oct. 16, 2001). Plaintiffs have discussed above the

common evidence that will be used to prove each element of an independent claim for medical monitoring—the availability of this evidence, as well as the fact that each Class Member has consumed a sufficient amount of VCDs, creates the necessary "commonality of interests" contemplated by the cohesiveness inquiry. *Gates*, 655 F.3d at 264.

As an alternative way of demonstrating cohesiveness, the Third Circuit has explained that for purposes of (b)(2) certification, the focus "is more heavily placed on the nature of the remedy sought." *Shelton*, 775 F.3d at 561. Accordingly, "injuries remedied through (b)(2) actions are really group, as opposed to individual injuries." *Barnes*, 161 F.3d at 143 n. 18.

Both Classes thus satisfy the cohesiveness requirement.

### D. In the Alternative, the Independent Claim Class Satisfies Rule 23(b)(3).

Plaintiffs propose that the Court may alternatively certify the Independent Claim Class under Rule 23(b)(3). *See* Dkt. No. 1709 at ¶ 538. Certification of medical monitoring classes under both Rule 23(b)(2) and (b)(3) is not uncommon. *See Telectronics*, 172 F.R.D. at 286; *Donovan*, 268 F.R.D. at 28. Rule 23(b)(3) requires that "questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3). The Independent Claim Class satisfies both requirements.

#### 1. Predominance.

Predominance requires that common questions should "predominate over any questions affecting only individual members." *Amgen Inc. v. Conn. Ret. Plans & Trust Funds*, 133 S. Ct. 1184, 1194 (2013). There is sufficient overlap between the commonality requirement of Rule 23(a), and the cohesiveness inquiry under Rule 23(b)(2), such that the analysis of those requirements above is applicable here to establish predominance. *See Danvers Motor Co., Inc. v. Ford Motor Co.*, 543 F.3d 141, 148 (3d Cir. 2008) (noting the overlap between commonality and

predominance); *Gates*, 655 F.3d at 269.

Notably, with respect to the requirement that common questions of law predominate, as one court explained, "[o]f the states that do recognize medical monitoring as an independent cause of action, the elements of such a claim appear to be same." *In re Baycol Prods. Litig.*, 218 F.R.D. at 211-12.[12]

As Plaintiffs have shown above using the *Redland* elements as an example, common evidence establishes each element of a medical monitoring claim. Because the elements do not vary among the relevant jurisdictions, and in light of Defendants' common course of wrongful conduct towards the Class, common evidence predominates over individual issues or defenses. For example, the Lifetime Cumulative Threshold establishes a common minimum exposure to nitrosamines that will govern Plaintiffs' entitlement to medical monitoring class wide—and therefore, subsumes all individual issues such as dosages, supply chain, and frequency of valsartan use, streamlining both Class membership identification and resolution on the merits.

**2. Superiority.**

In determining whether superiority is met, the Court must "balance, in terms of fairness and efficiency, the merits of a class action against those of 'alternative available methods' of adjudication." *Georgine v. Amchem Prods., Inc.*, 83 F.3d 610, 632 (3d Cir. 1996), *aff'd*, 521 U.S. 591 (1997). Here, a class action is superior to the other methods of adjudication available: individual plaintiffs could not establish a classwide medical monitoring program for the benefit of all those exposed to contaminated valsartan, and the Third Circuit has characterized medical

[12] *In re Welding Fume Prods. Liability Litig.*, 245 F.R.D. 279, 292 (N.D. Ohio) (finding that elements of medical monitoring claim in Arizona, Ohio, and Pennsylvania were all substantially similar); *see also Bell v. 3M Co.*, 344 F. Supp. 3d 1207, 1225 (D. Colo. 2018) (listing identical elements of medical monitoring claim); *Abbatiello v. Monsanto Co.*, 522 F. Supp. 2d 524, 539 (S.D.N.Y. 2007) (finding that New York would recognize medical monitoring claim using elements identical to those in *Redland*).

monitoring as primarily a group remedy.

Specifically, Rule 23(b)(3)(A) supports certification because Class Members do not have an interest in pursuing litigation through separate actions against Defendants—the remedy sought, a notice and medical monitoring protocol, would not rationally be brought an individual plaintiff. *See Day v. NLO*, 851 F. Supp. 869, 886 (S.D. Ohio 1994) ("To administer medical monitoring piecemeal is unworkable."); *In re Warfarin Sodium Antitrust Litig.*, 391 F.3d 516, 533–34 (3d Cir. 2004) ("The superiority requirement 'asks the court to balance, in terms of fairness and efficiency, the merits of a class action against those of alternative available methods of adjudication.'" (internal quotations omitted). Rule 23(b)(3)(B), which concerns the extent and nature of any litigation already brought by Class Members, is satisfied because Medical Monitoring Plaintiffs are not aware of any other pending litigation outside this MDL. In accordance with Rule 23(b)(3)(C), the most efficient method is to concentrate litigation through one trial. *See Heinz v. Dubell Lumber Co.*, No. 19-8778, 2020 WL 6938351, at *8 (D.N.J. Nov. 25, 2020). The Court has extensive knowledge of the claims through the supervision of the MDL, which favors certification. Without certification, the most likely result is "many of the claims [will] not be[] brought," and class members' claims will not be vindicated. *Id.*

Finally, Rule 23(b)(3)(D) requires an assessment of the manageability of this action. To underscore both the cohesiveness of the Independent Claim Class, and the manageability of a class action, Plaintiffs have submitted a Medical Monitoring Trial Plan and Structure as Exhibit F, which shows that the Independent Claim Class' claims can be heard in a single, orderly, efficient, and fair trial.

## VI. CONCLUSION

Plaintiffs respectfully request that the Court grant their motion for class certification, appoint them as Class Representatives, and appoint Class Counsel.

Dated: November 10, 2021

Respectfully submitted,

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*MDL Plaintiffs' Co-Lead Counsel, on behalf of the Plaintiffs' Executive Committee and all Plaintiffs*

**CERTIFICATE OF SERVICE**

I hereby certify that on this 10th day of November, 2021, I caused a true and correct copy of the foregoing to be filed and served upon all counsel of record by operation of the Court's CM/ECF system. In addition, I certify that unredacted versions of the foregoing will be served contemporaneously upon liaison counsel for Defendants as well as the Court.

/s/ *Rachel Geman*
Rachel Geman